Individual Safety Report

1393797-3-00-01*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Knoll Pharmaceutical Company

Approved by FDA on 3/22/94

Mfr report # USA005504

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier: [redacted] in confidence
2. Age at time of event: 48 yrs or Date of birth: [redacted]
3. Sex: ☒ female ☐ male
4. Weight: ____ lbs or 152.862 kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 03/??/95

4. Date of this report (mo/day/yr): 01/15/99

5. Describe event or problem

Elevated liver function

A physician reports that a female (48 years old at the time of the event) initiated Vicodin ES (dose unknown) in 1991 for pain. She developed elevated liver function tests (exact labs and values unknown) approximately in Mar-1995. The event persisted for 6 weeks. Vicodin ES was discontinued and the event abated.

6. Relevant tests/laboratory data, including dates

elevated liver function tests: exact labs values and dates unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Concomitant disease(s): severe car accident in 1991; allergies to PCN, baby aspirin, Tylenol, some antibiotics (unspecified), some antidepressants (unspecified); diabetes; arthritis; controlled cholesterol and triglycerides; post-MI and CVA (dates *

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 VICODIN ES
#2

2. Dose, frequency & route used
#1 UNK
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 ??-???-91 to ??-APR-95
#2

4. Diagnosis for use (indication)
#1 pain
#2

5. Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 UNKNOWN
#2

7. Exp. date (if known)
#1 Unk
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
#1 NI
#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

Name: NITROBID Dates: UNK to UNK Duration: a few years
Name: TICLID Dates: UNK to UNK Duration: a few years
Name: LASIX Dates: UNK to UNK Duration: a few years *

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
Knoll Pharmaceutical Company
3000 Continental Drive - North
Mount Olive, New Jersey 07828-1234

2. Phone number: (973) 426-2600

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

UNITED STATES

4. Date received by manufacturer (mo/day/yr): 11/17/98

5. (A)NDA # 89-736
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☐ 15-day
- ☐ 10-day ☒ periodic
- ☒ Initial ☐ follow-up # ____

8. Adverse event term(s)
HEPATIC FUNCTION ABNORMAL NOS

9. Mfr. report number
USA005504

E. Initial reporter

1. Name, address & phone #
Dr. [redacted]
[redacted] Street
Suite [redacted]
[redacted] USA *

FEB 1 0 1999

2. Health professional?
☒ yes ☐ no

3. Occupation
PHYSICIAN (MD)

4. Initial reporter also sent report to FDA
☐ yes ☐ no ☒ unk

B.7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[continuation:] unknown); gout; treated with Synthroid for an unspecified disorder
Risk factor(s): nonsmoker
Race: UNK

C.10. Concomitant medical products and therapy dates (exclude treatment of event)

[continuation:] Name: SYNTHROID Dates: UNK to UNK Duration: a few years
Name: ZANTAC Dates: UNK to UNK Duration: a few years
Name: allopurinol Dates: UNK to UNK Duration: a few years
Name: LOPID Dates: UNK to UNK Duration: a few years
Name: Lipitor Dates: UNK to UNK Duration: a few years
Name: TRILISATE Dates: UNK to UNK Duration: a few years
Name: insulin Dates: UNK to UNK Duration: a few years

E.1. Name, address & phone #

[continuation:] Phone: [redacted]

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